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Kagan Binder, PLLC
221 Main Street North
Suite 200
Stillwater, MN 55082

EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/740,698	VARNER ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-74,76-119,122-127,129 and 132-140* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-74, 76-119, 122-127, 129, and 132-140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 68-74, 76-91, 93-97, 99-109, 111-119, 122-127, 129, and 132-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al (U.S. Patent No. 5,466,233) in view of Rosenman et al (U.S. Patent No. 6,478,776).

Weiner et al disclose an implantable ocular drug delivery device (10) having a non-linear shaped body member (12, 14a) comprising a tube and that is implanted within a patient eye to deliver a drug substance to the patient via the body member and a cap element (16) (see Figures 1-5). The cap element is at the proximal end of the body member as see in Figure 1 and is sized to provide a cross-section larger than the cross-section of the non-linear body member such that the cap element abuts an incision through which the device is inserted to stabilize the device. In lines 1-11 of column 8, Weiner et al disclose the body member being positioned within the vitreous fluid. The device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member (see Figure 14). The tube has a cross-sectional diameter approximately equal to that of an incision through which the device is being inserted (see Figure 14). With respect to claims 69-71, the device body member comprises at least five deviations from a linear path as seen by the multiple

surfaces of the body member. The cap element is seen to be capable of being in contact with a patient eye outer surface when the body member is inserted into the eye. The cap element mates the body member at a proximal end of the device as seen in Figure 1. The cap element is in contact with the body member. With respect to claim 76, Weiner et al disclose the device comprising a therapeutic agent for delivery to the patient during use of the device (line 33 of column 10 to line 27 of column 11). With respect to claims 77 and 78, Weiner et al disclose the device body comprising a polymer that comprises a therapeutic substance that can be delivered to the patient eye (lines 28-67 of column 8). With respect to claims 83-86 and 100-102, Weiner et al disclose a method of treating a patient comprising delivering a delivery device comprising a non-linear shaped body member (12, 14a) comprising a tube having at least five deviations from a linear path and a cap element (16) at a proximal end, inserting the device into a patient's eye through an incision, the incision being approximately the same size as the outer diameter of the tube forming the body member, whereby the body member resides in the vitreous fluid of the patient's eye and the cap element remains outside the incision through which the device is inserted and abuts the outer surface of the eye to stabilize the device, and allowing a therapeutic agent to be administered to the patient via the body member. The cap element is seen to remain outside of and abut the incision as seen in Figure 14 where the device of Figure 1 is inserted into a patient eye such that the body member resides in the patient eye. With respect to claim 89 and 105, see line 33 of column 10 to line 27 of column 11. With respect to claims 90, 91, 106, and 107, the body member comprises a

polymer and comprises a therapeutic substance that can be delivered to the patient eye (lines 28-67 of column 8). With respect to claim 108, the cap element is in contact with the outer surface of the patient eye. With respect to claim 109, the device is inserted by screwing the device into the eye. With respect to claim 116, Weiner et al disclose an implantable ocular drug delivery device having a non-linear shaped body member (12, 14a) that is implanted within a patient eye during use of the device to deliver a drug substance to the patient eye via the body member and a cap element (16) (see Figure 1). The cap element is sized to prevent the cap element from passing through an incision through which the device is inserted and the cap element is configured to mate against the patient eye outer surface while the body member is inserted to the eye. The device is implantable within the vitreous fluid of a patient eye. With respect to claim 117, the incision comprises a sclerotomy. With respect to claim 118, the device is implanted in a minimally invasive surgical procedure. With respect to claim 119, the device is implanted at the pars plana (lines 29-50 of column 5 and line 24 of column 14 to line 5 of column 16). With respect to claims 122-127 and 132-137, see line 46 of column 8 to line 52 of column 9 and line 65 of column 9 to line 32 of column 10. With respect to claim 138, the tube has a circular cross-section.

Weiner et al disclose the implantable drug delivery device substantially as claimed. With respect to claim 68-73, even though Weiner et al disclose a non-linear shaped body member comprising a tube, Weiner et al are silent on the specifics of the tube of the body member comprising provided in a coil or zig-zag shape along its entire length from its proximal end to its distal end. Rosenman et al disclose a delivery device

having a non linear shaped body member (12) comprising a tube provided in a coil or zig-zag shape along its entire length from its proximal end to its distal end that is implanted within a patient and a cap element (56) which abuts an incision through which the device is inserted to stabilize the device (see Figures 9-12, 14, 15, 17-19). The device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member (see lines 62-67 of column 10 and lines 16-26 of column 11). The device body member comprises at least five deviations from a linear path as seen in Figures 18 and 19. The device body member comprises a helical shape or a substantially Z-shape as seen in Figures 18 and 19. Rosenman et al disclose implanting the device within the heart and other organs of the body which can include the eye (lines 8-28 of column 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube forming the body member of Weiner et al with a coil or zig-zag shape along its entire length from its proximal end to its distal end as taught by Rosenman et al as both Weiner et al and Rosenman et al disclose an implantable device for controlled drug release which is secured in a patient's body (Weiner et al: lines 26-48 of column 3 and lines 1-27 of column 8, Rosenman et al: lines 40-59 of column 5 and lines 16-67 of column 11) and Rosenman et al disclose that it is well known to provide an implantable device having a non linear shaped body member comprising a tube provided in coil or zig-zag shape along its entire length from its proximal end to its distal end to allow for proper positioning and securement of the device in the desired location in a patient's body where the device will provide controlled drug release. Since the device of Rosenman et

al is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member, providing the tube forming the body member of Weiner et al with a coil or zig-zag shape would result in the device of Weiner et al being insertable through an incision approximately the same size as the outer diameter of the tube forming the body member.

Weiner et al disclose the drug delivery device substantially as claimed. With respect to claims 79 and 129, Weiner et al disclose an implantable ocular drug delivery device (10) having a non-linear shaped body member (12, 14a) comprising a tube or post (12) and an anchoring region (14a). However, Weiner et al are silent on the specifics of the body member comprising a tube wound into a coil shape. Rosenman et al disclose an implantable drug delivery device having a body member (12) comprising a tube wound in a coil or shape as seen in Figures 9-12, 14, 15, 17-19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube or post of Weiner et al wound into a coil shape as taught by Rosenman et al as both Weiner et al and Rosenman et al disclose sustained release of a drug through an implantable device and Rosenman et al disclose that it is well known to provide an implantable device with a coil or zig-zag shape because the coil or helically shaped body member allows for the drug to be released in all directions when the device is implanted into the desired location (lines 21-36 of column 10). Since the device of Rosenman et al is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member, providing the tube forming the body member of Weiner et al with a coil or zig-zag shape would result in the device

of Weiner et al being insertable through an incision approximately the same size as the outer diameter of the tube forming the body member.

Weiner et al disclose the method and device substantially as claimed. With respect to claims 83-88 and 111, Weiner et al disclose an implantable ocular drug delivery device (10) having a non-linear shaped body member (12, 14a) comprising a tube or post (12) and an anchoring region (14a). Even though Weiner et al disclose a non-linear shaped body member comprising a tube, Weiner et al are silent on the specifics of the tube of the body member comprising a coil or zig-zag shape or being wound into a coil shape. Rosenman et al disclose a delivery device having a non linear shaped body member (12) comprising a tube provided or wound in a coil or zig-zag shape that is implanted within a patient and a cap element (56) which abuts an incision through which the device is inserted to stabilize the device (see Figures 9-12, 14, 15, 17-19). The device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member (see lines 62-67 of column 10 and lines 16-26 of column 11). The device body member comprises at least five deviations from a linear path as seen in Figures 18 and 19. The device body member comprises a helical shape or a substantially Z-shape as seen in Figures 18 and 19. Rosenman et al disclose implanting the device within the heart and other organs of the body which can include the eye (lines 8-28 of column 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube or post of Weiner et al with a coil or zig-zag shape as taught by Rosenman et al as both Weiner et al and Rosenman et al disclose sustained release of a drug through an implantable

device and Rosenman et al disclose that it is well known to provide an implantable device with a coil or zig-zag shape because the coil or helically shaped body member allows for the drug to be released in all directions when the device is implanted into the desired location (lines 21-36 of column 10). Since the device of Rosenman et al is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member, providing the tube forming the body member of Weiner et al with a coil or zig-zag shape would result in the device of Weiner et al being insertable through an incision approximately the same size as the outer diameter of the tube forming the body member.

As to claims 93-97, 99-109, and 116, Weiner et al disclose the device and method substantially as claimed. Weiner et al disclose an implantable ocular drug delivery device (10) having a non-linear shaped body member (12, 14a) comprising a tube or post (12) and an anchoring region (14a). However, Weiner et al are silent on the specifics of the body member being coil-shaped or zig-zag shaped where the device is inserted through an incision smaller than the cross-section of the coil-shaped body member. Rosenman et al disclose an implantable drug delivery device having a coil-shaped or zig-zag shaped body member as seen in Figures 9-12, 14, 15, 17-19 where the device is inserted through an incision smaller than the cross-section of the coil-shaped or zig-zag shaped body member (see lines 62-67 of column 10 and lines 16-26 of column 11). The device body member comprises a helical shape or a substantially Z-shape as seen in Figures 18 and 19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube or post of

Weiner et al with a coil shape or zig-zag shape as taught by Rosenman et al as both Weiner et al and Rosenman et al disclose sustained release of a drug through an implantable device and Rosenman et al disclose that it is well known to provide an implantable device with a coil or zig-zag shape because the coil or helically shaped body member allows for the drug to be released in all directions when the device is implanted into the desired location (lines 21-36 of column 10). Since the cap element of Weiner et al is sized to provide a cross-section larger than the cross-section of the non-linear body member, providing the body member of Weiner et al with a coil shape would result in the cap element of Weiner et al being sized to provide a cross-section larger than the cross-section of the coil-shaped body member.

As to claims 139 and 140, Weiner et al disclose the tube or post (12) of the non-linear shaped body member (12, 14a) having a cross-section of about 1 mm to about 4 mm in diameter at the second end (40) of the tube or post (12) (lines 12-18 of column 6). As seen in Figures 1 and 5, both the conical and the capsule shaped tube or post (12) have a cross-section at the first end (22 or 26) of the tube or post (12) that is less than the diameter at the second end. Therefore, the tube or post (12) of Weiner et al has a cross-section of 0.5 mm or less in diameter or has a circular cross-section in the range of 0.25 to 0.5 mm in diameter at the first end (22 or 26) of the tube or post (12) as, when the cross-section of the second end (40) is about 1 mm in diameter, the cross-section at the first end (22 or 26) will be 0.5 mm or less in diameter as seen in Figures 1 and 5. The non-linear shaped body member (12) of Rosenman et al comprising a tube provided or wound in a coil or zig-zag shape is disclosed as the tube having an inside

diameter of up to 0.20 mm (lines 29-30 of column 15). In lines 20-22 of column 8, Rosenman et al disclose that the tube that is provided or wound in a coil or zig-zag shape is typically 0.41 mm in outside diameter and 0.20 mm in inside diameter. Therefore, Rosenman et al disclose the tube having a cross-section of 0.5 mm or less in diameter and having a circular cross-section in the range of 0.25 to 0.5 mm in diameter. Furthermore, providing the tube or post of Weiner et al with a coil or zig-zag shape as taught by Rosenman et al would result in the tube with the coil or zig-zag shape having a cross-section of 0.5 mm or less in diameter or having a circular cross-section in the range of 0.25 to 0.5 mm in diameter as it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube or post of Weiner in a coil or zig-zag shape with a cross-section of 0.5 mm or less in diameter or a circular cross-section in the range of 0.25 to 0.5 mm in diameter as taught by Rosenman et al as both Weiner et al and Rosenman et al disclose the diameter of the tube of the body member having a cross-section of 0.5 mm or less or in the range of 0.25 to 0.5 mm. In addition, the instant disclosure describes the parameter of the diameter of the tube as being merely preferable (see lines 9-14 of page 20 of the specification) and, as such, this parameter is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

3. Claims 92, 98, and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al in view of Rosenman et al as applied to claims 83, 93, and 99 above, and further in view of Johnson (U.S. Patent No. 5,972,027). Weiner et al

and Rosenman et al disclose the method substantially as claimed. However, Weiner et al and Rosenman et al are silent on the specifics of the device comprising a shape memory material. Johnson discloses an implantable drug delivery device with a non-linear body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium (lines 39-56 of column 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiner et al and Rosenman et al to make the device of a shape memory material as taught by Johnson as Johnson teaches that it is well known to make an implantable device from a shape memory material to provide a bio-compatible and strong device.

Response to Arguments

4. Applicant's arguments, see line 15 of page 14 to line 4 of page 15, filed December 16, 2010, with respect to the objection to the specification have been fully considered and are persuasive. The objection to the specification has been withdrawn.

5. Applicant's arguments filed December 16, 2010 have been fully considered but they are not persuasive.

As to Applicant's arguments in lines 17-26 of page 15, the claims are not drawn to the body member having a non-linear path. The claims are drawn to a non-linear shaped body member and Weiner et al disclose a non-linear shaped body member (12, 14a) as shown in Figures 1-5 where the outer surface of the body member provides a non-linear shape to the body member. Also, the non-linear shaped body of Weiner et al does deviate from a linear path as the surface of the non-linear shaped body deviates

from a linear path. The broadest reasonable interpretation has been applied to a “non-linear” shaped body member to indicate a body member which has a surface which does not follow a straight line. Applicant’s arguments, that to understand if a body member is linear or non-linear, the "longitudinal axis" of the device must be followed, are not persuasive as the surface of the device can also be followed to determine if a body member has a linear shape or a non-linear shape.

Applicant’s arguments in line 27 of page 15 to line 16 of page 16 are not persuasive. Weiner et al disclose a non-linear shaped body member as disclosed above and the rejections of the claims are not based on modifying the shape of the body member from linear to non-linear. Furthermore, even though Weiner et al disclose a preferred insertion method of the device where an injection provides for a substantially straight injection, Weiner et al also disclose that it is preferred that the device (10), which has a non-linear shaped body member (12, 14a) is inserted with a "slight twirling motion" (lines 2-4 of column 15).

As to Applicant’s arguments in lines 17-30 of page 16, Weiner et al disclose a cross sectional diameter of the body member of 0.5 mm or less or a diameter in the range of 0.25 mm to 0.5 mm. Weiner et al disclose the tube (12) of the non-linear shaped body member (12, 14a) having a cross-section of about 1 mm to about 4 mm in diameter at the second end (40) of the tube (lines 12-18 of column 6). As seen in Figures 1 and 5, both the conical and the capsule shaped tube (12) have a cross-section at the first end (22 or 26) of the tube or post (12) that is less than the diameter at the second end and, when the cross-section of the second end (40) is about 1 mm, the

cross-section at the first end (22 or 26) will be 0.5 mm or less in diameter or in the range of 0.25 mm to 0.5 mm in diameter as seen in Figures 1 and 5.

As to Applicant's arguments in line 31 of page 16 to line 22 of page 17, the teachings of Rosenman et al are relevant to the claimed subject matter. Rosenman et al disclose implantable devices for controlled drug release which is considered to be in a similar area of medical treatment and relevant to the claimed subject matter. Furthermore, an ophthalmologist or a surgeon using the device of Weiner et al would be familiar with the general field of implantable devices for delivering drugs into a patient's body, and, thus, would be familiar with the implantable devices such as those taught by Rosenman et al. In response to applicant's argument that Rosenman et al is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the prior art of Rosenman et al is in the field of delivering therapeutic agents and medicaments to the patient's body and is reasonably pertinent to the securement or anchoring of the implantable device in the patient's body. In lines 5-43 of column 16, Rosenman et al disclose that the disclosed devices and methods can be adapted to treat conditions within other organs of the body, and since the eye is an organ of the body, the disclosed devices and methods are considered to be capable of being adapted to treat conditions within the eye. In addition, one skilled in the art of ocular drug delivery at the time of the invention would see the teaching of the coil or zig-

zag shape to allow for proper positioning and securement in the desired location in a patient's body as being applicable to modify the device of Weiner et al.

As to Applicant's arguments in line 23 of page 17 to line 17 of page 18, the device of Rosenman et al is capable of abutting an incision through which the device is inserted to stabilize the device. The device of Rosenman et al has a cap element (56) which is capable of abutting an incision or a cut made in a body tissue or organ such as an incision made in the myocardium. The primary reference of Weiner et al discloses a cap element (16) which abuts an incision through which the device is inserted to stabilize the device. The specific teachings of the cap element of Rosenman et al have not been applied to modify the device or method of Weiner et al. It was merely indicated that the device of Rosenman et al has a cap element that is capable of abutting an incision. Also, one of skill in the art at the time of the invention in view of the cited art would have understood that an implantable device such as the implantable ocular device of Weiner et al could be stabilized in a material that is mainly fluid with solid tissue only at the outer surface without the disclosure of Applicant's invention.

Applicant's arguments in line 18 of page 18 to line 3 of page 19 are not persuasive. The disclosure of Rosenman et al pertains to providing a device that can deliver a drug or medicament to a specific location such that the drug or medicament does not escape to an undesired location. The prior art of Rosenman et al is in Applicant's field of endeavor and is pertinent to the particular problem with which Applicant is concerned as Rosenman et al disclose implantable devices and methods for inserting the implantable devices such that a drug or medicament can be delivered

to a specifically desired location in the patient's body such as to organs of the body. Since in lines 5-43 of column 16, Rosenman et al disclose that the disclosed devices and methods can be adapted to treat conditions within other organs of the body, and since the eye is an organ of the body, the disclosed devices and methods are considered to be capable of being adapted to treat conditions within the eye and, thus the prior art of Rosenman et al is reasonably pertinent to the particular problem with which the Applicants are concerned.

As to Applicant's arguments in lines 4-33 of page 19, the obviousness rejection of the claims is supported with an articulated reasoning with rational underpinning. The rejection of the claims states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube or post of Weiner et al wound into a coil or zig-zag shape as taught by Rosenman et al as both Weiner et al and Rosenman et al disclose sustained release of a drug through an implantable device and Rosenman et al disclose that it is well known to provide an implantable device with a coil or zig-zag shape because the coil or helically shaped body member allows for the drug to be released in all directions when the device is implanted into the desired location (lines 21-36 of column 10). This does not indicate that the drug is not capable of being released from the device of Weiner et al in all directions. The device of Weiner et al is capable of allowing and does allow the drug to be released from all directions as disclosed in line 12 of column 8 to line 19 of column 9 where the drug would diffuse from the matrix (76) in all directions. Rosenman et al disclose that the drug begins to escape in all directions as soon as the structure is inserted into tissue

(lines 21-36 of column 10). Thus, modifying the tube of Weiner et al to have the shape of a coil or zig-zag as taught by Rosenman et al would also allow for the drug to be released from all directions with respect to the coil or zig-zag shape and allow for the drug to begin to escape more quickly from all directions due to the larger outer surface of the coil or zig-zag shape as compared to the non-linear shape of Weiner et al. Therefore, the motivation for providing the coil or zig-zag shape to the tube of Weiner et al is to allow the drug to begin to escape and be released in all directions through the larger outer surface of the coil or zig-zag shaped tube as soon as the structure is inserted into the desired location.

As to Applicant's arguments in lines 1-6 of page 20, there is teaching, suggestion, and motivation by both Weiner et al and Rosenman et al to provide the tube forming the non-linear body member of Weiner et al with the coil or zig-zag shape as taught by Rosenman et al. First, Weiner et al disclose that portion (14a) of the non-linear shaped body member can be of any potential configuration that would enable the portion (14a) to secure the device in the eye (lines 2-11 of column 6) and that portion (12) of the non-linear shaped body member can be of any configuration or shape as long as the portion (12) is capable of providing sustained, controlled delivery of the drugs (lines 3-11 of column 8). Therefore, there is teaching and suggestion to modify the device of Weiner et al. Secondly, Rosenman et al disclose an implantable device having a coil or zig-zag shape along the entire length of the body member where the device is for controlled drug release while being secured in a patient's body (lines 40-59 of column 5 and lines 16-67 of column 11). Rosenman et al disclose that the device

can be adapted to treat conditions within the organs of the body, and since the eye is an organ of the body, the disclosed device is considered to be capable of being adapted to treat conditions within the eye. Thus, there is teaching, suggestion, and motivation to provide the body member of Weiner with the coil or zig-zag shape of Rosenman et al. Furthermore, one skilled in the art at the time the invention was made would be motivated to provide the tube of the non-linear body member of Weiner et al with a coil or zig-zag shape along the entire length of the body member as taught by Rosenman et al as Rosenman et al teach that the tube with a coil or zig-zag shape along the entire length of the body member will allow for proper positioning and securement of the device in the desired location in the patient's body where the drug is to be released. Also, one would be motivated to provide the tube of Weiner et al with a coil or zig-zag shape along its entire body length as the coil or zig-zag shape would both provide an anchoring region equivalent to the anchoring region (14a) of Weiner et al and provide a post for sustained controlled drug release equivalent to the post (12) of Weiner et al.

Applicant's arguments in lines 12-17 of page 20 are not persuasive. Weiner et al and Rosenman et al disclose the devices and methods as recited in independent claims 83, 93, and 99 as detailed above.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Bhisma Mehta/
Examiner, Art Unit 3767